

### **REMARKS**

Applicants respectfully request reconsideration. Claims 1-13 and 33-45 were previously pending in this application. In this response, Applicants have amended independent claims 1, 11, 12 and 13 to remove the requirement that the recited methods stimulate angiogenesis. No new claims have been added. As a result, claims 1-13 and 33-45 are pending for examination with claims 1, 11, 12, and 13 being independent claims. No new matter has been added.

Claims 1-13 and 33-45 stand rejected under 35 U.S.C. §112 first paragraph, as failing to comply with the enablement requirement. More specifically, the Patent Office states that the specification does not fully enable the intended use language “stimulating angiogenesis” of the claims as previously pending, citing In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Applicants respectfully request reconsideration of this rejection in view of the above amendments and the remarks below.

While Applicants contest the merits of the present rejection, as described below, solely for the purpose of expediting allowance of the application, Applicants have elected to amend the claims to remove the intended use language directed to stimulating angiogenesis. Since the enablement rejection appears to be directed exclusively to the “stimulating angiogenesis” aspect of the rejected claims, and since the Patent Office in the Office Action appears to agree that the other aspects of the claims are enabled by the specification, removal of this language by the present amendments renders the basis for the rejection moot, and withdrawal of the rejection for this reason is requested.

Regarding the merits of the rejection, in citing Wands, the Patent Office appears to consider only six of the eight factors that must be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. §112. The Patent Office states that the nature of the invention involves a method of use of an implantable delivery device which causes blood to pool in myocardial tissue, and that the state of the prior art for treating myocardial tissue ischemia includes commonly used PTCA and bypass grafts, both of which involve, via different means, introducing blood into myocardial tissue. The Patent Office appears to agree that the specification adequately describes the manner in which the bodies are implanted into the myocardial tissue and the use of the implanted bodies to bring about pooling of blood.

However, the Patent Office states that the unpredictability of the *peptide art* is very high and that *other attempts* have resulted in restenosis, incomplete revascularization and a sudden closure of the blood vessel, so that one of ordinary skill in the art would not have concluded at the time the specification was filed that he/she would have been able to achieve the intended use of stimulating angiogenesis recited in the claims without undue experimentation.

Applicants respectfully disagree. As an initial matter, Applicants respectfully point out that any unpredictability that may exist in the peptide art is not relevant to enablement of the claimed invention, which does not involve the use of peptides. In addition, while the Office Action refers to other attempts that have resulted in restenosis, incomplete revascularization and sudden closure of the blood vessel, no supporting documentation or references have been provided, rendering this contention simply the unsupported opinion of the Examiner. If the rejection is to be sustained, Applicants further request documentary evidence supporting and describing the nature of these “attempts” by others. As the Patent Office can appreciate, it is difficult or impossible for the Applicants to respond by describing how the failures of others may or may not be applicable to the methods described and claimed by the present application without knowing the nature of the attempts made by others on which the Patent Office is relying. Indeed, the Patent Office’s own examination guidelines clearly indicate that such support is required.<sup>1</sup> If no supporting documentation or references can be provided, Applicants respectfully request withdrawal of this aspect of the rejection.

In addition, the Office Action states that no working examples are provided which would lead one to believe the disclosed device can be used to promote angiogenesis. However, it is not necessary for working examples to be provided for the enablement requirement of 35 U.S.C. §112 to be met.<sup>2</sup> Moreover, Applicants contend that the embodiments of the claimed invention described in the specification would have led one of ordinary skill in the art to conclude that the invention as recited in the rejected claims could be practiced using the teachings of the specification without an undue level of experimentation. Indeed, in support of this contention, Applicants point the Patent Office’s attention to Deckelbaum, L. I., “Cardiovascular

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<sup>1</sup> MPEP §2144.03(a) states that “It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known.” In this regard, the Applicants believe that facts on which the Patent Office is relying for supporting the rejection are not capable of “instant and unquestionable demonstration.”

<sup>2</sup> MPEP §2164.02 states that “Compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed.”

Applications of Laser Technology”, *Lasers in Surgery and Medicine*, 15:315-341 (1994), that teaches that blood supplied to myocardial sinusoids, which connect to the myocardial microcirculation give rise to angiogenesis based on evidence of revascularization. In this regard, it is believed that based on the state of the art, as reflected in for example this reference, one of ordinary skill in the art at the time Applicants’ invention was made, upon learning of the novel and inventive methods taught by Applicants’ specification for supplying blood to the myocardium, e.g. as a direct result of blood pooling within the myocardium as recited in claims 1 and 11, would have believed that angiogenesis in the supplied region would occur.

In view of the above amendments and remarks, it is believed that independent claims 1, 11, 12, and 13 are in condition for allowance. Because claims 2-3, 5-10, and 33-45 depend either directly or indirectly from independent claim 1, these claims should also be allowed.

Accordingly, withdrawal of the rejection of claims 1-13 and 33-45 under 35 U.S.C. §112 is respectfully requested.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. B0953.70014US00.

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Respectfully submitted,

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